

A randomised controlled trial of longer-term clinical outcomes and cost-effectiveness of Standard And New Antiepileptic Drugs

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 25/04/2003	Overall study status Completed	☐ Protocol
Last Edited 14/04/2020	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

HTA 95/13/01

Study information

Scientific Title

A randomised controlled trial of longer-term clinical outcomes and cost-effectiveness of Standard And New Antiepileptic Drugs

Acronym

SANAD

Study objectives

We propose a pragmatic parallel group Randomised Controlled Trial (RCT) comparing monotherapy with clinicians' first choice standard drug (carbamazepine or valproate) versus appropriate comparators from among the new antiepileptic drugs.

More details can be found at <http://www.nets.nihr.ac.uk/projects/hta/951301>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Epilepsy

Interventions

Monotherapy with clinicians' first choice standard drug (carbamazepine or valproate) versus appropriate comparators from among the new antiepileptic drugs

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Carbamazepine, valproate

Primary outcome(s)

Primary outcomes will be retention time on randomised drug and time to one year remission of seizures.

Key secondary outcome(s)

Secondary outcomes will include psychosocial measures and impact on direct medical costs.

Completion date

31/03/2006

Eligibility

Key inclusion criteria

Patients recently suffering seizures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

2437

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/09/1998

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The Walton Centre

Liverpool

United Kingdom

L9 7LJ

Sponsor information

Organisation

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	carbamazepine trial results	24/03/2007		Yes	No
Results article	valproate trial results	24/03/2007		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	results	01/04/2019		Yes	No
Other publications	HTA monograph	01/10/2007		Yes	No